

510(k) SUMMARY

MAY 11 2007

Submitter Name: Custom Scientific
Submitter Address: 7021 Haverford Drive
Dallas, TX 75214
Contact Person: Mr. Timothy Mulone

Phone Number: 214.343.3688
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Date Prepared: August 31, 2006

Device Trade Name: **Craniotech Bone Transport Reconstruction Plate (BTRP)**

Device Common Name: External Mandibular Fixator and/or Distractor
Classification Number: 21 CFR 872.4760
Classification Name: Bone Plate
Product Code: MQN

Predicate Device: K010139; Zurich Distraction System; KLS-Martin L.P.

Statement of Intended Use: The Craniotech Bone Transport Reconstruction Plate (BTRP) system includes devices intended as a bone stabilizer, lengthening and/or transport device when correction of congenital or developmental bone deficiencies or post-traumatic or post-surgical defects of the mandible (including ramus, body, alveolar ridge, symphysis) and mid-face bones require gradual distraction.

Device Description: The device contains a reconstruction plate and screws of TiAl6V4 titanium alloy, and a stainless steel bone transport unit, activation screw and flexible cable.

Comparison to the Predicate Devices: Based upon the intended use, design, materials, and the testing conducted, it can be concluded the BTRP is substantially equivalent to the predicate device in terms of intended use, safety and effectiveness.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 11 2007

Craniotech ACR Device, LLC
C/O Ms. Patsy J. Trisler
5600 Wisconsin Avenue, # 509
Chevy Chase, Maryland 20815

Re: K062572

Trade/Device Name: Craniotech Bone Transport Reconstruction Plate
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: MQN
Dated: May 4, 2007
Received: May 7, 2007

Dear Ms. Trisler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Chiu Lin", with a stylized flourish at the end.

Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) Number (if known):

K062572

Device Name:

Craniotech Bone Transport Reconstruction Plate

Indications for Use:

The Craniotech Bone Transport Reconstruction Plate (BTRP) system includes devices intended as a bone stabilizer, lengthening and/or transport device when correction of congenital or developmental bone deficiencies or post-traumatic or post-surgical defects of the mandible (including ramus, body, alveolar ridge, symphysis) and mid-face bones require gradual distraction.

Prescription Use x
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Posted November 13, 2003)



(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K062572